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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,945	01/14/2002	Binie V. Lipps	FWLPAT015US	5192

7590 06/28/2005

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EXAMINER	
SZPERKA, MICHAEL EDWARD	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/047,945	LIPPS ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *1-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Sno

DETAILED ACTION

1. Applicant's amendment and response received April 10, 2005 is acknowledged.

Claims 1-18 are pending in the instant application.

Claims 9, 10, 14, 15, and 17 have been amended.

Claims 1-8 stand withdrawn for the reasons of record set forth in the office action mailed January 24, 2005.

Claims 9-18 are under examination in this action as they read to the elected species of IgE, SEQ ID NO:1 and diabetes.

Specification

2. Applicant is thanked for submitting an amendment to the specification to incorporate the handwritten correction found on page 7.

Information Disclosure Statement

3. Applicant has requested on page 10 of the reply filed April 10, 2005 conformation that art developed in corresponding PCT application PCT/US03/01044 has been considered in the instant application. The examiner has considered the art indicated on the IDS submitted June 5, 2002, a signed copy of which was returned with the office action mailed January 24, 2005. If there are additional references for which Applicant wishes conformation concerning their consideration by the examiner in this application, these references should be submitted on a supplemental IDS.

Claim Objections

4. The objection to claims 9 and 10 has been withdrawn due to applicant's amendment of the claims to replace containing with comprising (claim 9) and contains with comprises (claim 10).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. The rejection of claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, has been withdrawn due to applicant's amendment to the claims to remove the requirement of diagnosis as part of the method of peptide administration.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 9-18 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record set forth in the office action mailed January 24, 2005.

Applicant's arguments filed on pages 9 and 10 of the response received April 10, 2005 have been fully considered but they are not persuasive. Applicant has argued that the claims require only that the administration of peptides derived from an inhibitor of snake venom metalloproteinases reduce free IgE in serum, and that the claims do not require this reduction to be therapeutic in any human disease condition or that said disease conditions are caused by or can be diagnosed by the presence of high levels of IgE. Applicant also argues that since the claims as amended on April 10, 2005 recite "to reduce serum level of free IgE" this language no longer requires IgE levels to be reduced and therefore the part of the rejection based upon the failure of Applicant to show that the instant invention reduces IgE levels should be withdrawn. The examiner respectfully disagrees.

The examiner agrees with applicant that the instant claims do not require any causation, diagnosis, or effectiveness in treating any human disease. However, the examiner has read the claims in light of the specification, wherein it is taught that reducing IgE levels is therapeutically beneficial in diseases such as asthma, type II diabetes, depression and autoimmunity (see particularly the paragraph that spans pages 8 and 9). Applicant is reminded that a method of reducing IgE levels or free IgE serum levels has no utility in and of itself. Why would anyone want to reduce IgE unless the reduction of IgE did something, such as treat allergy? If Applicant believes that reducing IgE has a utility other than treating human disease, Applicant is invited to clearly point out where support for such a utility can be found in the specification. As was discussed in the office action mailed April 24, 205, applicant has not established

that the administration of Applicant's peptide has any credible, statistically significant therapeutic benefit in the treatment of any human disease.

Applicant has also argued that the claims now recite reducing free IgE and as such the statistical significance of Applicant's data is no longer at issue. As pointed out in the office action mailed January 24, 2005, data presented by Applicant concerning the administration of the peptide to reduce IgE, such as that in tables 3-7 is not statistically relevant. Further, in experiments 1 and 2 found on page 8 of the instant specification, administration of the peptide somehow causes the IgE not to be detected by ELISA. As discussed in the prior office action of January 24, 2005 on pages 6-8, these experiments do not prove that the peptide binds IgE. The disclosed experiments only raise the question of where has the peptide gone? Experiment 1 is a closed system wherein saliva is mixed with either PBS or the peptide (what it is dissolved in is not specified) in a closed tube, incubated at 37^0C for one hour, and they assayed for the presence of IgE. The peptide is not an enzyme and therefore it could not have degraded the IgE. It is unlikely that the presence of the peptide caused all of the IgE to precipitate from solution, since although this would effectively remove IgE from the solution to be tested for the presence of IgE, Applicant would have seen the precipitate at the bottom of the tube. IgE is significantly larger than the administered peptide, so even if the peptide does bind IgE, it could not possibly mask all epitopes present on IgE that could be bound by anti-IgE antibodies. The identity of the anti-IgE antibody used by Applicant is not disclosed, but use of a different antibody, especially polyclonal sera that recognizes multiple epitopes of IgE, would likely reveal that both samples contained

the same amount of IgE. Given that the specification does not disclose the source or identity of the anti-IgE antibody used by Applicant it is not possible for anyone to practice the claimed invention since the anti-IgE antibody used by Applicant potentially has unique characteristics that would not be shared by all anti-IgE antibodies. Also, there is no indication that the experiments conducted by Applicant were ever repeated. As such, the findings of Applicant's experiments 1 and 2 can also be quite reasonably explained as being due to random chance and not due to any effect of the peptide itself on IgE levels.

In summary, Applicant has not provided any evidence which indicates that the data disclosed by Applicant is due to anything more than random chance. As such, a skilled artisan would not be able to perform Applicant's claimed method without an undue amount of experimentation.

9. No claims are allowable.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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June 9, 2005

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